

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated January 22, 2007 (hereinafter Office Action) have been considered. Claims 1-66 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The Applicant acknowledges the restriction requirement between claims 1-32 and 48-66, identified in the Office Action as Invention I, and claims 33-47, identified in the Office Action as Invention II. The Applicant further acknowledges that claims 1-32 and 48-66 were elected via phone on January 5, 2007, without traverse.

Claims 1, 2, 4, 5-7, 9, 17-19, 21, 24, 32, 48, 49, 54-56, and 66 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,146,029 by *Ellinwood, Jr* (hereinafter "*Ellinwood*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Ellinwood* does not teach each and every element and limitation of independent claims 1, 18, 48, and 55, and therefore fails to anticipate these claims.

The Applicant's independent claims 1, 18, 48, and 55 each recite, among other features, some variation of a driver apparatus detachably coupled to the implantable medical device, the driver apparatus configured to facilitate phoresis delivery of a pharmacological agent from one or both of the can and the lead.

In discussing phoresis, the Applicant's Specification states that "[t]wo non-limiting examples of phoresis are electrophoresis and sonophoresis. Electrophoresis is generally understood as an electrochemical process in which colloidal particles and/or macromolecules with a net electric charge migrate under the influence of an electric potential . . . Sonophoresis is generally understood as a sonochemical process in which

colloidal particles and/or macromolecules migrate under the influence of pressure waves, such as continuous wave or burst-mode ultrasound.” (Page 12, Lines 1-8). The Applicant respectfully submits that phoresis is a concept that is not contemplated in the *Ellinwood* reference.

Ellinwood discloses an implantable medication dispensing system. (Abstract). *Ellinwood* teaches that a mechanical piston and bellows mechanism is used to pump and dispense fluid medication. (Col. 8, Lines 61-67; Figs. 7-13). *Ellinwood* also discloses the use of a mechanical cam and solenoid for controlling and timing the medication release. (Col. 9, Lines 14-39; Figs. 10-13). *Ellinwood* does not disclose any other dispensing mechanisms or medication driving means, including phoresis.

Because *Ellinwood* does not contemplate medication delivery means beyond the mechanical means discussed above, the Applicant respectfully submits that *Ellinwood* does not teach phoresis or a phoresis driver apparatus, as recited in each of independent claims 1, 18, 48, and 55. Accordingly, *Ellinwood* fails to teach each and every element and limitation of independent claims 1, 18, 48, and 55, and therefore cannot sustain a rejection of these claims.

Dependent claims 2, 4, 5-7, 9, 17, 19, 21, 24, 32, 49, 54, 56, and 66, which are dependent from independent claims 1, 18, 48, and 55, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Ellinwood*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4, 5-7, 9, 17, 19, 21, 24, 32, 49, 54, 56, and 66 are also not anticipated by *Ellinwood*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4, 5-7, 9, 17-19, 21, 24, 32, 48, 49, 54-56, and 66 as being anticipated by *Ellinwood* is not sustainable, the withdrawal of which is respectfully requested.

Claims 1, 2, 4, 5, 9, 16-19, 21, 22, 31, 32, 48, 49, 53-56, 58, 65, and 66 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,178, 349 by *Kieval* (hereinafter "*Kieval*").

The Applicant's independent claims 1, 18, 48, and 55 each recite, among other features, some variation of a cardiac electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation. The Applicant respectfully submits that *Kieval* does not disclose cardiac electrical stimulation.

Kieval teaches an implantable nerve stimulator. (Col. 2, Lines 57-59). The embodiments disclosed by *Kieval* include only stimulating nerves that communicate with the brain and/or brain stem. (Col. 5, Lines 3-27). *Kieval* states that the disclosed nerve stimulation only indirectly influences organs (except for the brain) because the stimulated nerves relay to nerve centers, such as the brain, where the stimulated nerve center can then reflexively change organ function. (Col. 4, Lines 33-48). With respect to the heart, *Kieval* states that "[s]elective stimulation of the right or left vagus nerves 44, 46 may bring into control the heart rate and blood flow without resorting to direct stimulation of the heart 22" (Col. 4, Lines 33-36; emphasis added). The Applicant respectfully submits that *Kieval* does not disclose cardiac nerve stimulators, nor direct stimulation of the heart.

Each of Applicant's independent claims 1, 18, 48, and 55 recite some variation of a cardiac electrode configured for one or both of cardiac monitoring and cardiac electrical stimulation, which is clearly not disclosed in *Kieval*.

In regard to the rejection of independent claims 1, 18, 48, and 55, the Office Action states that "*Kieval* further teaches that the electrode stimulates a nerve that affects cardiovascular activity (see column 3, lines 11-16; which is being interpreted as cardiac electric stimulation because it is electrical stimulation corresponding to cardiac function)." The Applicant respectfully submits that such an interpretation of "cardiac electrical stimulation" is in error, and not an interpretation that one of ordinary skill in the art would make, particularly in light of the Applicant's Specification.

In examination proceedings, “claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Johnson*, 558 F.2d 1008, 1016, 194 USPQ 187, 194 (Cust. & Pat. App. 1977).

The Applicant respectfully submits that “cardiac electrical stimulation” would be interpreted by one of ordinary skill in the art as requiring at least delivering electrical stimulation to the heart, particularly when the “Field of Invention” is stated as being “implantable cardiac cardioverters/defibrillators” and the Specification further states that “[t]ypical implantable cardioverter/defibrillators (ICDs) include one or more endocardial leads to which at least one defibrillation electrode is connected. Such ICDs are capable of delivering high-energy shocks to the heart, interrupting a ventricular tachyarrhythmia or ventricular fibrillation, and allowing the heart to resume normal sinus rhythm. ICDs may also include pacing functionality.” (Page 1, Line 28 – Page 2, Line 3; emphasis added).

In light of the Specification, the Applicant’s claim recitations of “cardiac electrical stimulation” cannot be interpreted as electrical nerve or brain stimulation that only indirectly influences the heart and does not deliver electrical stimulation to the heart.

As such, the Applicant respectfully submits that *Kieval* does not teach cardiac electrical stimulation, as recited in each of independent claims 1, 18, 48, and 55. Therefore, *Kieval* fails to teach each and every element and limitation of independent claims 1, 18, 48, and 55, and cannot sustain a rejection of these claims.

Dependent claims 2, 4, 5, 9, 16, 17, 19, 21, 22, 31, 32, 49, 53, 54, 56, 58, 65, and 66, which are dependent from independent claims 1, 18, 48, and 55, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Kieval*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4, 5, 9, 16, 17, 19, 21, 22, 31, 32, 49, 53, 54, 56, 58, 65, and 66 are also not anticipated by *Kieval*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4, 5, 9, 16-19, 21, 22, 31, 32, 48, 49, 53-56, 58, 65, and 66 as being anticipated by *Kieval* is not sustainable, the withdrawal of which is respectfully requested.

Claims 3, 8, 10-16, 20, 23, 25-27, 29-31, 50-53, 57, and 59-65 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood*. Claims 22 and 58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood* in view of U.S. Patent No. 6,282,444 by *Kroll et al* (hereinafter "*Kroll*"). Claim 28 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood* as applied to Claim 27 above, and further in view of U.S. Patent No. 6,295,474 by *Munshi*. Claims 3, 6-8, 10-15, 20, 23-25, 26-30, 50-52, 57, 63, and 64 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Kieval* in view of U.S. Patent No. 5,628,730 by *Shapland et al.* (hereinafter "*Shapland*"). Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Kieval* in view of U.S. Patent No. 5,749,909 by *Schroepel et al.* (hereinafter "*Schroepel*").

Each of dependent claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 depend from one of independent claims 1, 18, 48, and 55. Each of the rejections listed above use one of the *Ellinwood* or *Kieval* references to teach or suggest the elements and limitations of the independent claims, and use the other references for various elements and limitations of rejected dependent claims. With reference to the above discussions of the *Ellenwood* and *Kieval* references, the Applicant respectfully submits that *Ellenwood* and *Kieval* each respectively fails to teach or suggest each and every element and limitation of independent claims 1, 18, 48, and 55. Moreover, *Kroll*, *Munshi*, *Shapland*, and *Schroepel* fail to properly supply the missing teachings or suggestions, even through the Office Action does not rely on these references for such purposes.

As such, while the Applicant does not acquiesce to the particular rejections to dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim

depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 not made obvious by *Kieval* or *Ellinwood*, even in combination with *Kroll*, *Munshi*, *Shapland*, or *Schroeppel*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, stated interpretations of the claims or cited references, capable configurations, obvious design choices, proposed advantages, stated problem solutions, performance expectations, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching or suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

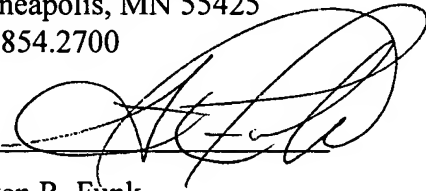
Authorization is given to charge Deposit Account No. 50-3581 (GUID.626PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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